

## REMARKS

Reconsideration and withdrawal of the rejection and the allowance of all claims now pending in the above-identified patent application (*i.e.*, Claims 22-30) are respectfully requested in view of the foregoing amendments and the following remarks.

At the outset, it should be recognized that the present invention provides a radioactive dose dispensing apparatus for automatically filling a container with a required radioactive dose in a sterile environment that is useful in the practice of nuclear medicine, in which a radioactive dose is able to be provided in a container, such as, for example, a plunger-operated syringe, in an automated fashion, thereby obviating the need for any person to physically handle any radioactive material. As now practiced in the art, dose fractionation of required radioactive solutions is largely a manual process performed by a medical technician behind a lead-shielded screen for minimizing exposure to radiation. This manual procedure is rather time-consuming, as the medical technician is required to successively withdraw iterations – small volumes of the radioactive tracer – until the targeted dose amount is reached.

More particularly, the state of the art involves the use of a base radioactive solution (*i.e.*, the stock solution), the radioactive content of which is known at the time that this base radioactive solution is stored for later use. During the period of storage, radioactive decay occurs, so that after a period of time, the radioactivity of the stock solution is no longer precisely known at the time of later usage. In addition to radioactive decay, the radioactive metal elements settle in solution and are therefore different concentrations

throughout the stock solution as time passes.

The presently claimed invention overcomes the drawbacks of the manual procedure, and problems associated with the delayed use of the radioactive stock solution that are well known to the prior art, by providing accurate means for automatically dispensing individual doses of a radioactive solution into vials, or syringes, under aseptically-controlled conditions, while minimizing the exposure of radiation to a medical technician, or other operator, which would otherwise be associated with the manual manipulation of radioactive solutions. Specifically, the claimed invention measures the radioactivity of the mixed solution on an immediate basis, so that its radioactivity dose is precisely known at the time of use with sequential batches having radioactivity measurements conducted in the same manner.

As now most broadly claimed, the present invention provides a radioactive dose dispensing apparatus for automatically filling a container with a required radioactive dose in a sterile environment, which includes a container, preferably formed as a plunger-operated syringe, and means for radiation shielding of the radioactive dose dispensing apparatus. Further, means are provided for controlling a mix of radioactive stock solution and dilution stock solution, as well as means for detecting radioactivity of the mix of the radioactive stock solution and the dilution stock solution. In a departure from the prior art, the means for controlling a mix of radioactive stock solution and dilution stock solution results in automatically diluting the radioactive stock solution with the dilution stock solution as both the radioactive stock solution and the dilution stock solution

simultaneously pass into the container; the prior art teaching the separate step of diluting a radioactive isotope in a dilution vial, rather than via controlling the mix of the radioactive stock solution and the dilution stock solution. The claimed invention further includes means for automating the radioactive dose dispensing apparatus and calculating a required dose for controlling the radioactive dose being dispensed into the container, which means for automating the radioactive dose dispensing apparatus and calculating a required dose comprising a programmable logic controller operable in combination with a radiation detector.

As will be explained in greater detail hereinafter, nowhere in the prior art is such a novel and efficient radioactive dose dispensing apparatus for automatically filling a container with a required radioactive dose in a sterile environment, which automatically dilutes the radioactive stock solution with the dilution stock solution as both the radioactive stock solution and the dilution stock solution simultaneously pass into the container, either disclosed or suggested.

By the present amendments, Applicants have canceled Claims 11-19 and have now amended independent Claim 22 so that it incorporates all of the limitations of prior independent Claim 11 and further recites the inclusion of “means for automating said radioactive dose dispensing apparatus and calculating a required dose for controlling the radioactive dose being dispensed into said container,” which means for automating comprises “a programmable logic controller operable in combination with a radiation detector.” The use, in part, of a “programmable logic controller” for performing such

means was previously recited in dependent Claim 16. As part of the Examiner's rejection, the Examiner stated that the prior art of Cassel, U.S. Patent No. 5,911,252, discloses a "controller" and that the "intended use" previously recited in dependent Claim 16, as well as independent Claim 22, was not viewed as limiting the relevant claims beyond that which is taught, and may conceivably be performed, by the prior art. The recitation of a "means-plus-function" element for which a programmable logic controller is used, as taught by Applicants' invention, but not otherwise disclosed or suggested by the prior art of record, is intended to address the Examiner's valid point that, as previously presented, Claims 16 and 22 recited merely an intended use recitation for the "programmable logic controller," which statements of intended use were not entitled to patentable weight or otherwise limiting on the claims, so as to avoid the prior art. Cassel, as will be further explained, it submitted to neither teach nor suggest the automated means now recited by Applicants, nor does the applied combination of references render the claimed invention obvious.

Independent Claim 22, now the single independent claim pending in the instant patent application, has been broadened with respect to the "container," which may be, but is not required to be, a "plunger-operated syringe." The preferred embodiment of a plunger-operated syringe as being the container used for practicing the claimed invention is now recited in new dependent Claim 30. (Dependent Claims 23, 24 and 25 have been appropriate amended.)

Accompanying the present *Amendment in Response to the Final Office Action*,

Applicants are filing a *Request for Continued Examination* and formal *Petition for a Three-Month Extension of Time* for response, and remitting all required fees. Accordingly, the “finality” of the last Office Action should be withdrawn and the foregoing amendments presented herein entered, and considered on their merits, as a matter of right.

Turning now, in detail, to an analysis of the Examiner’s prior art rejections, in the final Office Action the Examiner has rejected the subject matter of prior independent Claim 11 as being obvious, pursuant to 35 U.S.C. §103(a), over Cassel, U.S. Patent No. 5,911,252, taken in view of Matsuno et al., U.S. Patent No. 5,039,863. With respect to Claim 11, the Examiner has contended that the primarily-applied reference of Cassel discloses a dose dispensing apparatus comprising a container, means for controlling a mixture of stock solution and dilution solution, in which the mixture is created as both the stock solution and the dilution solution pass into the container. The Examiner concedes that Cassel does not disclose means for radiation shielding of the dose dispensing apparatus nor means for detecting the radioactivity of the mixture. The Examiner has therefore secondarily-applied Matsuno for its contended disclosure of the features acknowledged to be absent from Cassel, and has concluded that it would have been obvious to have modified the apparatus of Cassel by adding radiation shielding and a radiation detector, in order to adapt the apparatus of Cassel for dispensing a radioactive solution, thereby yielding that which was previously claimed by Applicants in independent Claim 11.

The subject matter of prior independent Claim 11 is now recited as part of inde-

pendent Claim 22 (the obviousness rejection of Claim 11, *per se*, is submitted to now be moot), which further recites subject matter similar to that which the Examiner rejected as previously recited in dependent Claim 16. With respect to independent Claim 22 (which incorporates the subject matter of prior Claim 16), the Examiner has rejected Claim 22 over the same combination of art applied against Claim 11, and has further stated that the “programmable logic controller” recited in Claim 22 (with reference to the rejection of Claim 16) is disclosed by Cassel, which discloses the inclusion of a “controller.” The Examiner has further stated that the “controller” in Cassel “could operate” in combination with a radiation detector to control the dosage being dispensed into a syringe, and that the statements in prior Claim 22 (as incorporating the rejection of Claim 16) were statements of intended usage for the programmable logic controller of Applicants’ invention and do not limit the claim to the recited intended uses.

The Examiner is correct with respect to his legal statement that the functional recitation in independent Claim 22, prior to the instant amendment, did not further limit the claim to the recited use and, in so many words, that the stated use or purpose for the “programmable logic controller” was not entitled to patentable weight. As now recited in independent Claim 22 (and all remaining claims via dependency), Applicants’ invention incorporates “means for automating said radioactive dose dispensing apparatus and calculating a required dose for controlling the radioactive dose being dispensed into said container,” which includes “a programmable logic controller operable in combination with a radiation detector.” Applicants respectfully submit that the foregoing “means-plus-function” recitation, which includes a “programmable logic controller” and a

“radiation detector,” is a means that is neither taught nor suggested by Cassel, and that the structural limitation afforded by Applicants’ recitation of “means for automating said radioactive dose dispensing apparatus and calculating a required dose” is entitled to the patentable weight that the prior purely functional recitation for the “programmable logic controller” was not. While Applicants agree that the “controller” (though not a “programmable logic controller”) in Cassel “could operate” in a manner similar to the “means for automating said radioactive dose dispensing apparatus and calculating a required dose for controlling the radioactive dose being dispensed into said container,” Applicants respectfully contend that no teaching or suggestion of such means is found in Cassel.

To the contrary, Cassel teaches through its disclosure that the “controller **16** incorporates one or more dials, key pads, settable knobs or other input apparatus which may be utilized by the operator to input, into the controller, the desired a) concentration, and b) volume of injectate to be loaded into each of the receiving syringes **22**.” (*See, Cassel at Col. 5, lines 46-51*) It is therefore respectfully submitted that Cassel fails to teach or suggest the “automated” features of the present invention, which are manually performed by the applied prior art with the inherent drawbacks previously discussed, and neither discloses nor hints at the recited “means for automating said radioactive dose dispensing apparatus and calculating a required dose for controlling the radioactive dose being dispensed into said container,” which comprises “a programmable logic controller operable in combination with a radiation detector,” as now most broadly recited in independent Claim 22.

In view of the foregoing, it is respectfully contended that the subject matter of newly-amended independent Claim 22 is not obvious over Cassel, taken in view of Matsuno, and that the Examiner's 35 U.S.C. §103(a) rejection has now been overcome and should be appropriately withdrawn.

In view of the foregoing, it is respectfully contended that all claims now pending in the above-identified patent application (*i.e.*, Claims 22-30) recite a novel and efficient radioactive dose dispensing apparatus for automatically filling a container with a required radioactive dose in a sterile environment, which automatically dilutes the radioactive stock solution with the dilution stock solution as both the radioactive stock solution and the dilution stock solution simultaneously pass into the container, and which further includes means for automating the radioactive dose dispensing apparatus and calculating a required dose for controlling the radioactive dose being dispensed, which is patentably distinguishable over the prior art. Accordingly, withdrawal of the outstanding rejection

and the allowance of all claims now pending are respectfully requested and earnestly solicited.

Respectfully submitted,

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- Enc.: 1. Petition for Three-Month Extension of Time for Response;
2. *Request for Continued Examination*, pursuant to 37 C.F.R. §1.114; and,
3. EFT for \$960.00 (*Request for Continued Examination* filing fee + Three-Month Extension Fee);

The Commissioner for Patents is hereby authorized to charge the Deposit Account of Applicant's Attorney (Account No. 19-0450) for any fees or costs pertaining to the prosecution of the above-identified patent application, but which have not otherwise been provided for.